

**THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

<b>DePuy Mitek, Inc.</b>	)	
<b>a Massachusetts Corporation</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	<b>Civil No. 04-12457 PBS</b>
	)	
<b>Arthrex, Inc.</b>	)	
<b>a Delaware Corporation and</b>	)	
	)	
<b>Pearsalls Ltd.</b>	)	
<b>a Private Limited Company</b>	)	
<b>of the United Kingdom</b>	)	
	)	
<b>Defendants.</b>	)	

**DePuy Mitek's Unopposed Motion For Leave To File a Sur-Reply To Defendants' Reply  
To DePuy Mitek's Response To Defendants' Objections To Magistrate's Order Granting  
DePuy Mitek, Inc.'s Motion To Preclude Arthrex, Inc. And Pearsalls, Ltd. From  
Supplementing Their Expert Reports And Depositions**

Plaintiff, Mitek submits this unopposed motion for leave to file a sur-reply to Defendants' Reply To DePuy Mitek's Response To Defendants' Objections To Magistrate's Order Granting DePuy Mitek, Inc.'s Motion To Preclude Arthrex, Inc. And Pearsalls, Ltd. From Supplementing Their Expert Reports And Depositions (D.I. 101). Pursuant to Local Rule 7.1(a)(2), the parties met and conferred on Tuesday, December 12, 2006 and Defendants' agreed not to oppose the filing of Mitek's sur-reply. Mitek's proposed sur-reply is attached to this motion. Accordingly, Mitek requests that its unopposed motion for leave be granted.

Date: December 15, 2006

DEPUY MITEK, INC.,  
By its attorneys,

/s/ Erich M. Falke

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**CERTIFICATE OF SERVICE**

I certify that I am counsel for DePuy Mitek, Inc. and that a true and correct copy of **DePuy Mitek's Unopposed Motion For Leave To File a Sur-Reply To Defendants' Reply To DePuy Mitek's Response To Defendants' Objections To Magistrate's Order Granting DePuy Mitek, Inc.'s Motion To Preclude Arthrex, Inc. And Pearsalls, Ltd. From Supplementing Their Expert Reports And Depositions** was served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

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Dated: December 15, 2006

/s/ Erich M. Falke  
Erich M. Falke

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**Plaintiff DePuy Mitek's Sur-Reply to Defendants' Reply To Defendants' Objections to the  
Magistrate's Order Granting DePuy Mitek, Inc.'s Motion to Preclude Arthrex, Inc. From  
Supplementing Their Expert Reports and Depositions**

**I. Arthrex's "Non-Virus" Reasons For Supplementing Were Heard & Rejected**

Mitek had the audio transcript of the hearing before Magistrate Bowler, which it was not aware of until Arthrex served it on December 5, 2006, transcribed (Ex. 1). The hearing transcript puts to rest Arthrex's argument that Magistrate Bowler did not appreciate the issues because much of the hearing argument addressed Arthrex's so-called non-virus reasons for supplementing. For example, Mitek explained (i) the prejudice that would result from supplementing for any of Arthrex's proposed reasons (*id.* at 3:3-4:17); (ii) Arthrex's failure to satisfy FED. R. CIV. P. 26(e)(1)'s condition precedent to supplementing of actually showing an error in the report regarding Dr. Gitis' diameter or "pliability" measurements (*id.* at 2:15-22; 11:24-12:18); and (iii) Arthrex had inexplicably delayed in raising these non-virus reasons (*id.* at 11:8-23). Likewise, Arthrex pointed out on several instances that it had non-virus reasons for supplementing (*id.* at 15:8-11; 17:19-18:6). Thus, the non-virus reasons for supplementing were argued.

Trying to spin its argument that the nonvirus reasons were not addressed at the hearing, Arthrex incorrectly states that Magistrate Bowler only asked two questions, that both questions related to the virus, and that first question related to evidence of the virus (D.I. 101 at 5). Arthrex is wrong on all accounts. Magistrate Bowler actually asked the following four questions: (1) what's the prejudice?; (2) do you have a trial date?; (3) where is the evidence?; and (4) what virus? (Ex. 1 at 3:2; 4:18-19; 13:2; 16:22). Notably, the answer to Magistrate Bowler's question regarding prejudice involved the prejudice from all of Arthrex's proposed supplementation (*id.* at 3:3-4:17).

Arthrex takes one statement from the hearing out of context and treats it as a detailed opinion. This is not a fair characterization of the ruling or the hearing. When ruling, Magistrate Bowler actually stated:

Well I am not satisfied that the explanation is good enough. He's saying there's a virus, but there's been no specific information or anything identifying a virus when or how or why. Motion to preclude granted.

(*id.* at 17:13-18). It is not clear whether the first statement was referring to just the virus reasons or the nonvirus reasons as well. But more importantly, after Magistrate Bowler ruled, Arthrex reargued its non-virus reasons for supplementing (*id.* at 17:19-18:6). After hearing Arthrex's "appeal," Magistrate Bowler reiterated, "I've already made a ruling" and did not elaborate on the basis for the Order (*id.* at 18:7-8). Thus, Arthrex's treatment of a snippet from the hearing as a detailed opinion is not a fair characterization of the proceedings. There is no detailed opinion addressing every point. To ascribe clear error based on a single statement is just not fair. Magistrate Bowler's Order is fully supported by the many reasons presented in the papers and at the hearing.

Also, although Mitek discussed the so-called diameter and pliability "errors" (*id.* at 10:1-19; 11:9-14), Arthrex chose not to mention these specific issues. But now Arthrex alleges that Magistrate Bowler clearly erred by not mentioning them. Arthrex's tactics are wrong. It is not fair for Arthrex to treat Magistrate Bowler's Order as a detailed opinion and require it to have mentioned these issues, when Arthrex failed to even discuss them.

## **II. Arthrex Has Not Shown Clear Error**

FED. R. CIV. P. 26(e)(1) requires as a condition precedent to supplementing that Arthrex first prove an inaccuracy that it was entitled to correct. Thus, just as Arthrex's virus claims provided no basis for supplementing because Arthrex had not proven a virus, Arthrex's non-virus reasons also fail because Arthrex failed to prove any typos or reporting errors.

**A. Diameter: Arthrex Did Not Satisfy Rule 26(e)(1)'s Condition Precedent Requiring That Dr. Gitis' Reported Diameter Measurements Were Inaccurate**

Arthrex alleges, based on ¶¶32 and 34 of Dr. Gitis' Affidavit (D.I. 101, Ex. 3), that Dr. Gitis' Report has a "typo" regarding his diameter measurements. But ¶32 of Dr. Gitis' Affidavit does not even mention diameter. Further, ¶34 of Dr. Gitis' affidavit actually states that "there *appears* to be a typographical error" (emphasis added), not that there *was* a "typo." Tellingly, Dr. Gitis was not willing to state under penalty of perjury that there was a typographical error. Nor could he because he had testified under oath that he measured the diameter with the wrong instrument, and he had testified in his Report and emphatically at his deposition that he measured 0.65 mm. numerous times (D.I. 93, Ex.3 at 3; Ex. 2 at 153:11-154:9; 165:1-4; & 172:23-173:7). Even when faced with evidence at his deposition -- that Arthrex submits for the first time here on reply -- that the measured diameter was out of range for a #2 size suture and different than what the manufacturer reported, Dr. Gitis confirmed his testimony (Ex. 2 at 168:10-173:7).

Thus, Dr. Gitis' report and deposition accurately describe his work, and contrary to Arthrex's assertions, the "*only* logical conclusion" is not a "typo" (D.I. 101 at 7). Rather, another logical conclusion fully supported by the record is that Dr. Gitis' Report is accurate regarding the work that he performed. To the extent Arthrex merely disagrees with a finding that was accurately portrayed in Dr. Gitis' Report, that is not clear error.<sup>1</sup>

**B. Pliability: Arthrex Did Not Satisfy Rule 26(e)(1)'s Condition Precedent Requiring That Dr. Gitis' Reported "Pliability" Test Was Inaccurate**

In his Report and at his deposition, Dr. Gitis testified that he performed a "pliability" test at a constant rate of *loading, not extension* (D.I. 93, Ex. 3 at 3; Ex. 2 at 84:16-20; 152:1-9; and 175:1-176:11). In an attempt to change this sworn testimony, Arthrex cites to only Dr. Gitis'

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<sup>1</sup> Arthrex argues that Dr. Gitis should be permitted to change his sworn testimony and that Mitek can just cross examine Dr. Gitis. But Arthrex's argument fails because Arthrex failed to first satisfy FED. R. CIV. P.'s 26 (e)(1)'s condition precedent to supplementation requirement.

conclusory affidavit at ¶14 (D.I. 101 at 7). But Dr. Gitis' last-minute, unsupported conclusion in light of the evidence to the contrary (D.I. 93 at 13-16) is insufficient to satisfy the condition precedent for supplementing. This is particularly true where, as explained in Mitek's Response, his "constant rate of extension" speculation arose after his virus excuse was shown to be irrelevant to his pliability testing methodology (*id.* at 15).

Arthrex incorrectly argues that Mitek stated that Dr. Gitis used a constant rate of extension (D.I. 101 at 8, 11). But Arthrex has no citation for this assertion because Mitek did not so state. Rather, Mitek's expert, Dr. Brookstein, pointed out that Dr. Gitis' data showed that he did not use the reported constant rate of loading of 0.33 kg./sec, but rather that the data were consistent with a *different rate of loading for each sample* (D.I. 93, Ex .14 at ¶¶16-17). Mitek has never said that a constant rate of extension was used.

**C. Knot Slippage-Strength Test: Arthrex Does Not Dispute That It Failed To Raise This Issue Before the Magistrate**

There is no dispute that Arthrex did not raise its knot slippage-strength test issues before Magistrate Bowler and first raised them now, about eight months after Dr. Gitis prepared his report. Thus, Arthrex has waived its argument regarding the knot slippage-strength test, and there cannot have been clear error.<sup>2,3</sup>

**III. Arthrex's Claims of No Prejudice Are Baseless**

Magistrate Bowler specifically asked about the prejudice that would result from Arthrex's supplementation (Ex.1 at 3:2-4:17). Just because Arthrex disagrees with the prejudice,

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<sup>2</sup> *Fireman's Ins. Co., of Newark, N.J. v. Todesca Equip. Co., Inc.*, 310 F.3d 32, 38 (1st Cir. 2002) (holding that arguments first raised in objections to Magistrate's ruling were waived); *Paterson-Leitch Co., Inc. v. Mass. Municipal Wholesale Elec. Co.*, 840 F.2d 895, 990-1 (1st Cir. 1988) (holding "categorically that an unsuccessful party is not entitled as of right to de novo review by the Judge of an argument never seasonably raised before the magistrate").

<sup>3</sup> Arthrex notes that Mitek did not dispute Dr. Gitis' new alleged methodology for his knot slippage strength tests. But Mitek did not dispute them because Arthrex first raised this issue on November 2, 2006, and Mitek has not had its experts analyze this new untimely speculation.



that is not clear error. In any event, Arthrex basically claims that there is no prejudice because Dr. Gitis should simply be believed. But Mitek has no basis for believing Dr. Gitis now, when he testified under oath contrary to what he now states; he stated that a virus infected all of his tests; he recanted his virus story; and now claims without any supporting documentation that the tests were conducted completely differently than originally stated. Thus, if Arthrex is permitted to supplement, Mitek and its experts will be forced to analyze extensive data, possibly conduct forensic analysis of his equipment to determine whether it can provide insight into how it actually worked, prepare expert reports from Mitek's experts, and bear the expense of further depositions of Dr. Gitis and Mitek's experts. Mitek should not be burdened with the expense of another round of expert discovery because of Dr. Gitis' sloppy work and untimeliness.

Arthrex also incorrectly contends that another round of expert discovery will not affect dispositive motions merely because it did not submit Dr. Gitis' work during the dispositive motion briefing. But the issues presented by Dr. Gitis' supposed tests are related to Arthrex's claims that FiberWire's coating has a material affect on the novel and basic characteristics of the claimed invention. This is a key issue to both summary judgment motions relating to infringement issues. It is fantasy to think that the outcome of those reports and depositions, which will be discussing the very issues before the Court, will not impact summary judgment, particularly where the parties are cognizant of the summary judgment briefing.

#### **IV. Conclusion**

Arthrex should not be permitted to make substantive changes to expert reports that were due over eight months ago, after the close of expert discovery, and after summary judgment motions have been filed and argued. After two rounds of briefing and a hearing, the facts remain the same; Arthrex did not satisfy the condition precedent to supplementation of showing an inaccuracy; there was no clear error.

Dated: December 15, 2006

DEPUY MITEK, INC.,

By its attorneys,

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# **EXHIBIT 1**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.	)	Civil No.
a Massachusetts Corporation,	)	04-12457 PBS
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
	)	
Arthrex, Inc.	)	
a Delaware Corporation and	)	Motion
	)	Proceedings
Pearsalls Ltd.,	)	
	)	
Private Limited Company of the	)	
United Kingdom	)	
	)	
Defendants	)	

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1 THE COURT: All right, well, it's  
2 plaintiff's Motion so I'll hear you.

3 MR. BONELLA: Thank you Your  
4 Honor.

5 THE COURT: Docket Entry No. 32  
6 for the record.

7 MR. BONELLA: Your Honor, we're  
8 here for plaintiff's motion to preclude defendant  
9 Arthrex from supplementing or redoing its expert  
10 reports after the close of expert discovery. And  
11 the reason Mitek's motion should be granted is  
12 basically for three reasons: One, it's too late.  
13 Expert discovery has closed and it's too late to  
14 redo expert discovery now.

15 Number two, in order to supplement  
16 expert discovery Arthrex was required as a  
17 condition precedent, had the burden of showing  
18 that there was an incorrect part of the report or  
19 part of the report is inadequate or incomplete under  
20 Rule 26(e)(1) for a reason that was not known to  
21 them during expert discovery when the reports were  
22 prepared. They haven't satisfied that burden.

23 Third, Your Honor, to allow  
24 supplementation at this late date would prejudice

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1 not only Mitek, but prejudice this Court.

2 THE COURT: What's the prejudice?

3 MR. BONELLA: Prejudice is  
4 threefold. One, it is going to be expensive. We  
5 are going to have to have another report from  
6 their expert, which requires us to depose them.  
7 We're also going to investigate the basis of that  
8 report, which requires looking at all types of  
9 data and analyses. This is a highly technical  
10 case, more so it is going to require attorney time  
11 and expert time

12 Also, our expert is going to have  
13 to analyze what he did and then prepare a report.  
14 They're going to want to depose our expert. And  
15 the report that he is going to prepare in  
16 response. If either are allowed to supplement, we  
17 are going to have more expert reports, more expert  
18 depositions, lots of attorney time.

19 This is a patent infringement  
20 case, highly technical and it's going to require a  
21 lot of work. That's one type of prejudice.

22 Another type of prejudice, Your  
23 Honor, this is a patent infringement case about a  
24 medical device, about a suture. Yet we have these

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1 claims now that there was a virus that somehow  
2 infected their expert's work, where they have  
3 interjected a whole new issue into the case,  
4 whether there was a virus or wasn't a virus. I'd  
5 like to talk a little bit about that, but that's a  
6 new issue. And if there was a virus, we would  
7 like to know what the virus was and how it  
8 affected his work. It goes right to his  
9 credibility, goes right to their expert's  
10 credibility as to whether or not there even was a  
11 virus and whether his data is accurate or  
12 inaccurate. And then this interjects an issue of,  
13 we need computer experts, we need software experts,  
14 we need virus experts to understand what this  
15 virus was and how it supposedly affected his work.  
16 So it interjects a whole new issue into a patent  
17 infringement case about sutures.

18 THE COURT: Do you have a trial  
19 date?

20 MR. BONELLA: We do not have a  
21 trial date, Your Honor. We had a hearing here in  
22 September 26 on dispositive motions and on the  
23 Markman issue. In a patent infringement action,  
24 there is a Markman hearing which construes the

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1 claims. That Markman hearing --

2 THE COURT: I know that much,  
3 counselor.

4 MR. BONELLA: Thank you, Your  
5 Honor.

6 The Markman hearing was held on  
7 September 26. Dispositive motions were heard at  
8 that time as well. So that's the other prejudice.  
9 If we're going to reopen expert discovery now,  
10 Your Honor, we're going to have more reports, more  
11 depositions. Expert discovery has already been  
12 briefed. It's already been heard. It's pending  
13 before The Court, and we shouldn't have to deal  
14 with experts now.

15 I would like to explain a little  
16 bit as to how this fits into the case and where we  
17 are in this case. It's a patent infringement case  
18 about sutures. Our client, Mitek, has a patent,  
19 and it covers sutures. Arthrex claims it doesn't  
20 infringe, and it provided these technical reports  
21 from a Dr. Gitis and from a Dr. Mukherjee.

22 Dr. Gitis did tests comparing two  
23 types of sutures, ones that are coated and ones he  
24 says are uncoated. He was trying to show that

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1 coating had an effect on the suture and,  
2 therefore, for legal reasons it took it outside  
3 the scope of Mitek's patent.

4 Their other expert, Dr. Mukherjee,  
5 relied on this report to say there was not  
6 infringement. That is how he fits into the case.

7 Where are we in this case? The  
8 case was filed November '04, fact discovery ended  
9 February 1, '06. Expert discovery went from March  
10 '06 to July '06. Immediately after that we had  
11 the dispositive motion hearing and the briefing,  
12 which has all been completed. Now we are just  
13 waiting for The Court's Order, after which we'll  
14 immediately move to pretrial and trial. That's  
15 where we are in this case.

16 How did this issue arise? When  
17 did it arise? That is the interesting part. We  
18 began expert discovery on March 4, '06 when  
19 Mitek's expert put forth a report showing  
20 infringement. Arthrex's experts responded on  
21 March 24, '06 showing what they've claimed to be  
22 tests showing non-infringement. Right after that  
23 we got that report we said, we don't quite  
24 understand all the work he's done. We would like

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1 to see the data underlying the test. We would  
2 like to see more procedures from his tests.

3 Mitek's expert wanted more  
4 information. We didn't get that information until  
5 May '06. This information was on a CD. It was  
6 data that was fully readable. There was no  
7 evidence of any virus whatsoever. We could fully  
8 read all the data. Our experts analyzed the data.  
9 They came up with their opinions about it and we  
10 received a supplemental report from Dr. Gitis on  
11 June 14, '06. He didn't address any of these  
12 issues then.

13 We took his deposition on June 21,  
14 '06. Nothing about a virus came up at that time.  
15 Expert discovery concluded in July '06. They were  
16 deposing our experts on the 26th and 27th, right  
17 before we moved into dispositive motion briefing.  
18 But on the 24th of July, we received an e-mail from  
19 opposing counsel, that is Exhibit 7 to our opening  
20 brief, saying that their expert had just informed  
21 them that he had a computer virus and that they  
22 were going to redo their entire reports.

23 This is the end of expert  
24 discovery and were moving to the dispositive

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1 motion phase. We were quite taken back from this.  
2 We had no evidence there was any virus. This  
3 virus didn't come up at his deposition. It didn't  
4 come up in any way in any of the documents that  
5 were produced. All of the data was fully  
6 readable.

7 We were surprised by this. We  
8 said, if you had a virus, let's see some of  
9 evidence of this virus. Show us the data, show us  
10 what's the name of this virus, how did it work.  
11 We received no information.

12 We had a meet and confer with  
13 opposing counsel. I said, well, if we don't have  
14 any information about this, we're going to file a  
15 motion to preclude this.

16 Immediately after that we got a  
17 communication saying that this expert, Dr. Gitis,  
18 would be unavailable for several weeks and be out  
19 of the country. Well, that may be the case, but he  
20 certainly has people working for him, he has his  
21 own company, he has a testing lab, he has people  
22 that ran these tests for him. We received no  
23 information, no information whatsoever.

24 To date we have received no

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1 information about this virus, we haven't received  
2 the name of the virus, what equipment it affected,  
3 how it affected them, how it affected the data  
4 that's completely readable. So, we filed our  
5 motion. And in response to the motion Arthrex  
6 took a new tactic. It said, well, the virus  
7 affected only portions of our data. It affected  
8 one test, they say now, the friction test that  
9 they did. And they want to redo the friction  
10 test.

11 One thing we pointed out in our  
12 motion, Your Honor, was that Dr. Gitis did a lot  
13 of work and a lot of work that didn't make sense,  
14 that had nothing to do whatsoever with the virus.  
15 So even if there was a virus, the virus provides  
16 no excuse whatsoever for redoing his work.

17 And in response to that Arthrex  
18 changed it tactic a little bit. It says in  
19 footnotes in its brief, it says in its opposing  
20 brief, it says, well, we were going to redo other  
21 things in our report, not for reasons of a virus,  
22 but because there's things in this that we think  
23 were just -- I don't know, appear to be  
24 inconsistencies.

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1 If you look at Exhibit 3 to  
 2 Arthrex's opposition, it is a declaration from Dr.  
 3 Gitis and he says in paragraph 33, for example,  
 4 they want to change -- they measured the diameter  
 5 of the suture, but he measured it and he did a bad  
 6 job. He used the wrong procedure to measure it.  
 7 And they want to come in now and say, oh, it was  
 8 just a typographical error in his report. And  
 9 even though he testified at deposition that he  
 10 measured it and got what he got, it was a  
 11 typographical error. But in his affidavit he  
 12 says, there appears to be a typographical error.

13 Pretty telling that in his  
 14 affidavit he wasn't even willing to say it was  
 15 actually a typographical error. And look at the  
 16 evidence that they put forth for a virus in his  
 17 affidavit. All he says is, in his report, I don't  
 18 understand my own data. Therefore, it must have  
 19 been a computer virus.

20 Well, obviously the other issues  
 21 are, it could be he just doesn't understand his  
 22 data, they ran the test wrong. There's lots of  
 23 reasons why the data isn't corrupt in any sense.  
 24 So Arthrex wants to take a new tactic now.

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1 It wants to change other portions of the report  
 2 for other reasons unrelated to the virus.

3 And also Arthrex says, well, we'd  
 4 like to make garden variety changes. That's the  
 5 word they used in their report, garden variety  
 6 changes. I don't know what a garden variety change  
 7 to an expert report is. I am not aware of those.

8 So that is how this arose. Now  
 9 where are we? Arthrex wants to do a virus -- redo  
 10 a friction test because of a virus, wants to  
 11 change how their diameter measurements were done,  
 12 calling them typographical errors, and wants to  
 13 redo -- testify as to how his pliability tests  
 14 were done. When their experts said it was done  
 15 one way, they want to come in with a new way now  
 16 and they want to make garden variety changes.  
 17 Well, none of this should be allowed. One reason  
 18 it should not be allowed is because it is totally  
 19 untimely. It's after expert discovery. It should  
 20 have been raised during expert discovery, it was  
 21 not. He's already supplemented. He had three  
 22 or four months to figure this out. He didn't do  
 23 it then, it's too late now.

24 Secondly, Rule 26(e)(1) requires

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1 them to come forward and show as a condition  
 2 precedent to supplementing that the information  
 3 that they want to supplement with wasn't available.  
 4 I think the case law makes that clear. The D.A.G.  
 5 Enterprises case 226 F.R.D. 95 says Rule 26 is not  
 6 a safe harbor for experts who don't do their work  
 7 right to come in later after the close of expert  
 8 discovery. Likewise the St. Germaine Corp. Case  
 9 2006 U.S. Dist. LEXUS 28263 says Rule 26 does not  
 10 grant a party a right to ignore court deadlines,  
 11 reopen discovery and find new facts and generate  
 12 new expert reports. The Avia v. Mazuna case 212  
 13 F.R.D. 306 and the Coles v. Perry case is also in  
 14 accord.

15 So the case law is clear that Rule  
 16 26(e)(1) does not permit supplementation just to  
 17 redo the expert's work when he does not do a good  
 18 job.

19 And that's what this is all about.  
 20 They want to do this friction test, but they  
 21 haven't come forward with evidence. We asked for  
 22 an offer of proof. Where is this evidence of a  
 23 virus? We still have not received any. They want  
 24 to change their diameter --

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1 THE COURT: All right, let me talk  
 2 to you about this. Where is the evidence?

3 MR. TAMBURRO: Your Honor, if I may  
 4 just clarify some of the history. Our expert,  
 5 Dr. Gitis, filed his expert report at the end  
 6 of March. He wasn't deposed. We received a  
 7 request for the underlying data. That's all  
 8 correct. We produced a disk with the data from  
 9 his files. He gave it to us. He had no reason to  
 10 believe there was anything inconsistent between  
 11 the data and his report. We produced it to the  
 12 other side at Dr. Gitis' deposition a couple of  
 13 months down the road which wasn't until June 21st.  
 14 I believe they asked him questions about his  
 15 tests, of course, and they asked him about all  
 16 these inconsistencies between what was in his  
 17 report and what was in the underlying data. At  
 18 the time, he had really next to no explanation  
 19 for these inconsistencies. He was baffled at his  
 20 deposition. He thought the test was going one  
 21 way. He didn't understand why there were  
 22 different numbers in the raw data, and he didn't --  
 23 that's the way he testified.

24 When he got back from his



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1 deposition, he went back to California. His  
 2 deposition was in D.C.. He went back to  
 3 California and did an investigation, did an  
 4 initial investigation and he found that the data  
 5 that he had in his raw data didn't match the  
 6 report. He asked around to the people that  
 7 actually did the tests, and he found that there  
 8 was at least one test that their calculations  
 9 were wrong, and he couldn't explain anything else  
 10 about the others, so he just figured it might have  
 11 been a virus. He couldn't figure out what was  
 12 wrong. He figured it might be a virus, that was  
 13 the information we had. That's what we told  
 14 plaintiff. That's what we had at the time.

15 Mr. Bonella asked us to do a whole  
 16 laundry list of things to investigate and we did.  
 17 We asked Dr. Gitis. We said, Dr. Gitis, you have  
 18 to give us more detail, what happened. He was  
 19 doing that. He got called out of the country on  
 20 an emergency for family reasons. I don't even  
 21 know what the details are. It was very personal.  
 22 Three weeks he was out of the country, and he was  
 23 just out of pocket. We asked him if anybody else  
 24 at the lab could help us during this time, and he

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1 said he would prefer to do this himself because  
 2 of all these inconsistencies that were involved  
 3 already. He didn't want anyone else getting  
 4 involved.

5 So, long story short, he did a  
 6 further investigation, and he found there was no  
 7 quote, unquote universal virus affecting the  
 8 entire testing. There were logical and reasonable  
 9 explanations for the inconsistencies in 80 percent  
 10 to 85 percent of the report, which we told -- the  
 11 plaintiff is aware of that now.

12 There is one test, only, out of the  
 13 seven he did, that he is not sure what happened to  
 14 the data. He had spent hours with his experts at  
 15 his own place, his software people and his testing  
 16 people. They cannot identify what happened to the  
 17 calculations for the so-called friction tests.  
 18 That's one of seven tests. The other six were  
 19 fine. He has explanations for what happened, and  
 20 we actually supplemented his report this week  
 21 earlier in the week to plaintiffs, so they are  
 22 aware of the reasons why there were these  
 23 inconsistencies with these other tests. He did  
 24 one test over, that's it. And the results of that

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1 test were produced to the plaintiff, and I told  
 2 them this week we are going to be getting them the  
 3 underlying data. We're going to make Dr. Gitis  
 4 available for deposition. There is no trial date,  
 5 so that prejudice is not a factor anymore. We are  
 6 going to expect their expert to make comments on  
 7 it. We haven't said we are going to need to  
 8 depose their expert on supplement. I would like  
 9 to see what he has say first. We're offering Dr.  
 10 Gitis for deposition. We understand they want to  
 11 take his deposition, but he's over blowing the  
 12 facts here. It's not that big of a deal for  
 13 reworking. It's one of seven tests. The other  
 14 six there is nothing to talk about. He explained  
 15 what went wrong. And, Your Honor, it was their  
 16 deposition questions that prompted him to look at  
 17 this stuff, and now we're telling them reasonable  
 18 explanations for it, and they're, that's not good  
 19 enough. Now we have to do all this work, and we  
 20 have to investigate, well, there is a virus, the  
 21 virus affected --

22 THE COURT: What virus?

23 MR. TAMBURO: To be honest, he is  
 24 not sure there is a virus, he can't explain it.

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1 His declaration for the one test, the friction  
 2 test, says, we are unable -- we cannot explain.  
 3 There is no reasonable explanation for the  
 4 inconsistencies. There is a calculation that's  
 5 done and it's intermittent. It's incorrect on an  
 6 intermittent basis, and so he cannot explain why  
 7 it's coming up wrong on an intermittent basis.  
 8 It's not wrong across the board. So he doesn't  
 9 know what the answer is. So that's why he redid  
 10 the test, and we produced the results of that  
 11 test, and they're entirely consistent with the  
 12 first test.

13 THE COURT: Well, I am not  
 14 satisfied that the explanation is good enough.  
 15 He's saying there's a virus, but there's been no  
 16 specific information or anything identifying a  
 17 virus, when or how or why. Motion to preclude is  
 18 granted.

19 MR. TAMBURO: Your Honor, if I  
 20 may. The virus really only went to one test. The  
 21 other six tests we've already explained that there  
 22 was no virus. We've given that to him, and we told  
 23 him what the explanation is. In fact, the raw  
 24 data is correct and the report is incorrect. And



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1 so all we did was say to the plaintiff, you're  
 2 correct, the raw data is inconsistent with what  
 3 was reported in the report. So what we are doing  
 4 now is supplementing the report. There is no  
 5 virus issue with respect to the other six tests at  
 6 all. So we're just saying --

7 THE COURT: I've already made a  
 8 ruling.

9 MR. TAMBURO: Thank you, Your  
 10 Honor.

11 MR. BONELLA: Thank you, Your  
 12 Honor.

13 THE COURT: Please stand and  
 14 recess.

15 (Hearing concluded.)  
 16  
 17  
 18  
 19  
 20  
 21  
 22  
 23  
 24

Page 19

1 C E R T I F I C A T E

2 I hereby certify that the  
 3 foregoing is a true and accurate transcription, to  
 4 the best of my ability, of the recorded  
 5 proceedings submitted for transcription in the  
 6 aforesaid matter.

7 I further certify that I am not  
 8 employed by, nor related to any party to this  
 9 action.

10 In witness whereof I hereby sign  
 11 this date:

12  
 13 December 12, 2006

14  
 15 Brigitte A. Strain, RPR  
 16  
 17  
 18

19 \_\_\_\_\_  
 20 Brigitte A. Strain, RPR  
 21 Dated:  
 22  
 23  
 24

21 (The foregoing certification of this transcript  
 22 does not apply to any reproduction of the same by  
 23 any means, unless under the direct control and/or  
 24 supervision of the certifying shorthand reporter.)

# **EXHIBIT 2**

1 IN THE UNITED STATES DISTRICT COURT FOR THE

2 DISTRICT OF MASSACHUSETTS

3 -----x  
4 DEPUY MITEK INC., a :  
Massachusetts Corporation, :  
5 Plaintiff, :  
6 vs. : Civil Action No.  
7 ARTHREX, INC., a Delaware : 04-12457  
Corporation, and PEARSALLS :  
8 LIMITED, a Private Limited :  
Company of the United :  
9 Kingdom, :  
10 Defendants. :  
11 -----x

12 Washington, D.C.

13 Wednesday, June 21, 2006

14 Videotape Deposition of:

15 DR. NORM GITIS,

16  
17 The witness, was called for examination by  
18 counsel for the Plaintiff, pursuant to notice,  
19 commencing at 8:15 a.m., at the law offices of  
20 Dickstein Shapiro Morin & Oshinsky LLP, 2101 L  
21 Street, Northwest, Washington, D.C., before  
22 Dawn A. Jaques, Certified Shorthand Reporter  
23 and Notary Public in and for the District of  
24 Columbia, when were present on behalf of the  
25 respective parties:

<p>82</p> <p>1 Q. Thank you. The testing that you did in 2 connection with this case in your reports, who 3 actually did the testing? 4 A. I did it together with two engineers in 5 my lab. 6 Q. Okay. And what engineers? 7 A. Michael Vinogradov and Vishal Khosla. 8 Q. Can you spell their names, please? 9 A. Michael V-I-N-O-G-R-A-D-O-V, Vinogradov, 10 and Vishal K-H-O-S-L-A, Khosla. One is from 11 Russia, one is from India. 12 Q. I'm going to guess Mr. Vinogradov is 13 from Russia? 14 A. Good guess. 15 Q. What did Mr. Vinogradov do with respect 16 to the test? What was his role? 17 A. He helped to set up the testers and 18 modules, and he did some of the tests together 19 with me. 20 Q. What tests did Mr. Vinogradov do? 21 A. Most of the tests, or maybe all of the 22 tests we kind of did together. 23 Q. So Mr. Vinogradov was involved in all 24 the tests? 25 A. Yeah, and same thing with Mr. Khosla.</p>	<p>84</p> <p>1 running, most of these tests took less than a 2 minute, right, actual running time? 3 A. Not really. Depends on what you call 4 the running. You have to set up the specimen, and 5 for some of them you have to make notes, so most 6 of them took several minutes. So, yeah, I was in 7 and out of the room during this test. 8 Q. And what percentage of the test did you 9 actually see? 10 A. Maybe between 25 and 50 percent. 11 Q. Okay. Is there any of the tests that 12 you didn't actually witness the test being done of 13 the tests that were done? Let me ask a better 14 question. 15 There's pliability tests that you've 16 described. Were you present for at least some of 17 the actual testing of the pliability samples for 18 pliability? 19 A. Yes, I was present in at least some of 20 each and every test, each type of test. 21 Q. Okay. So you weren't present the whole 22 time for this set-up and loading of each sample; 23 is that right? 24 A. That's correct. 25 Q. And from the tests that were done, data</p>
<p>83</p> <p>1 Q. How did their roles, Mr. Vinogradov and 2 Mr. Khosla's roles, differ? 3 A. Vinogradov is a more senior member of 4 the team, and he was involved fully in all the 5 tests that we did for Ethicon and U.S. Surgical, 6 and he was the only one who remembered something 7 from those old tests. 8 So Michael was more senior. He was 9 helping mostly in setting up the tests, and Vishal 10 was helping mostly in running the tests, and I was 11 like in and out. I was not there hundred percent 12 of the time. 13 Q. Okay. You weren't there 100 percent of 14 the time for the set-ups; is that right? 15 A. For all of it, for the set-ups and the 16 test. So they will do the set-up, I would come 17 approve or not approve, and then we would start 18 running tests. I would come out, come back and 19 see what is happening. 20 Q. Did you approve each set-up after it was 21 done before the test was run? 22 A. Yeah, of course. 23 Q. You visually looked at each set-up? 24 A. Yes. 25 Q. And in terms of when the tests were</p>	<p>85</p> <p>1 was generated, correct? 2 A. Yes. 3 Q. Okay. And all the data that was 4 generated, was that computer generated? 5 A. Yes. 6 Q. And then from the computer-generated 7 data, some calculations and results were 8 presented? 9 A. Yes. 10 Q. Who did the calculations? 11 A. Two of them, Michael and Vishal. 12 Q. Okay. What was your involvement in the 13 calculations? 14 A. We discussed the formula used, and I 15 checked the results. 16 Q. Did you check every result, or just kind 17 of spot check it? 18 A. I checked most of the results. 19 Q. Okay. Did you instruct Mr. Vinogradov 20 and Mr. Khosla as to how to -- as to what formulas 21 to use and how to generate the results from the 22 data? 23 A. How to generate results, I don't have to 24 instruct them. They know how to do it. 25 What formula to use, maybe it was not my</p>

22 (Pages 82 to 85)

<p>150</p> <p>1 right?</p> <p>2 A. Yes.</p> <p>3 Q. And then the second, is Z a zero?</p> <p>4 A. Yes.</p> <p>5 Q. Does that tell you this is where the</p> <p>6 test started after the preload was applied?</p> <p>7 A. I'm sorry, I have to think much more how</p> <p>8 to read this raw data.</p> <p>9 Q. Have you read the raw data before today</p> <p>10 that was used for the test?</p> <p>11 A. In my life? For this testing? No.</p> <p>12 Q. No, okay.</p> <p>13 A. I was looking only at the results.</p> <p>14 Q. Okay. Do you see the force column?</p> <p>15 A. Yes.</p> <p>16 Q. And at the time, .504 -- the force being</p> <p>17 applied to the specimen is .55 kilograms, right?</p> <p>18 A. Yes.</p> <p>19 Q. In your paper, in your page 3 --</p> <p>20 A. Yes.</p> <p>21 Q. -- of your report, you say the suture</p> <p>22 was preloaded with a tension of .5 kilograms.</p> <p>23 Preloaded suture was then pulled at a force,</p> <p>24 uniformly increasing at a rate of .33 kilograms</p> <p>25 per second.</p>	<p>152</p> <p>1 Q. And how is that controlled by the</p> <p>2 machine?</p> <p>3 A. It is the same servo-control as we</p> <p>4 discussed before.</p> <p>5 Q. It's measuring the force applied?</p> <p>6 A. Yes.</p> <p>7 Q. And it's programmed into it to increase</p> <p>8 it?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. So the column F sub Z, after the</p> <p>11 preload was applied, should that be going up at a</p> <p>12 rate of .33 kilograms per second?</p> <p>13 A. Yes.</p> <p>14 Q. What we're going to do is we have a CD</p> <p>15 with the data on it, if that's easier for you to</p> <p>16 look at.</p> <p>17 A. Yeah, it will be much easier.</p> <p>18 Q. It's Bates number ARM 25902. It's</p> <p>19 entitled CETR Raw Data.</p> <p>20 Do you have a later flight option?</p> <p>21 A. I thought we already finished.</p> <p>22 Q. Not quite.</p> <p>23 A. Go on with the rest of your questions.</p> <p>24 Q. Let me ask you while he's loading that</p> <p>25 up, I'll ask you a question. Page 3 at the top</p>
<p>151</p> <p>1 A. Yes.</p> <p>2 Q. Now, the uniform increase in rate you're</p> <p>3 talking about, is that uniform increase in the</p> <p>4 load that's applied to the specimen?</p> <p>5 A. Yes.</p> <p>6 Q. So you applied a .5 kilogram preload to</p> <p>7 specimen, right?</p> <p>8 A. Yes.</p> <p>9 Q. And then you increase that .5 kilogram</p> <p>10 preload at a rate of .33 kilograms per second</p> <p>11 uniformly, right?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. So at time --</p> <p>14 A. Uniform in time, yeah.</p> <p>15 Q. So at, say when the actual -- after the</p> <p>16 preload is applied, if you call that time zero,</p> <p>17 after the first second, the load applied should be</p> <p>18 .5 --</p> <p>19 A. Plus .33.</p> <p>20 Q. Would be .83?</p> <p>21 A. Yes.</p> <p>22 Q. And then it goes up?</p> <p>23 A. Yes, that's correct.</p> <p>24 Q. And it goes up uniformly, so for each --</p> <p>25 A. Yes.</p>	<p>153</p> <p>1 you say the suture of 50 millimeters in length.</p> <p>2 A. Yes.</p> <p>3 Q. So you used a 50 millimeter gauge line</p> <p>4 for each sample?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. What device did you use to</p> <p>7 measure the gauge lines?</p> <p>8 A. Caliper.</p> <p>9 Q. Caliper?</p> <p>10 A. Yeah.</p> <p>11 Q. Okay. And the diameter you say is .65</p> <p>12 millimeters.</p> <p>13 A. Measured this by caliper.</p> <p>14 Q. Did you measure the diameters?</p> <p>15 A. Yes.</p> <p>16 Q. Of each sample?</p> <p>17 A. Yes.</p> <p>18 Q. Every sample?</p> <p>19 A. Not every sample, but we measured it at</p> <p>20 least 10, 12 times, yeah.</p> <p>21 Q. And you always got .65 millimeters?</p> <p>22 A. Pardon me?</p> <p>23 Q. And you always got .65 millimeters?</p> <p>24 A. Yes.</p> <p>25 Q. For each sample?</p>



<p>154</p> <p>1 A. Yes.</p> <p>2 Q. So the coated and uncoated, did you</p> <p>3 measure the diameter?</p> <p>4 A. Yes.</p> <p>5 Q. And they were the same?</p> <p>6 A. Yes.</p> <p>7 Q. No difference?</p> <p>8 A. No difference as measured with a</p> <p>9 caliper.</p> <p>10 Q. Okay. I'm going to show you -- here's</p> <p>11 the computer. I think that your data is in files,</p> <p>12 and there's one that says "Modulus Raw Plots." Do</p> <p>13 you see that? I believe that's your --</p> <p>14 A. Yeah.</p> <p>15 Q. If you could open up that file of the</p> <p>16 modulus raw plots file. I think that's what we're</p> <p>17 looking at here. Is this coated or uncoated, or</p> <p>18 is it both?</p> <p>19 A. No, it seems to be opening. Hopefully</p> <p>20 it will open.</p> <p>21 Q. That's the uncoated graph, right?</p> <p>22 A. Maybe I will reduce magnification.</p> <p>23 Yeah.</p> <p>24 Q. Can you find -- we were looking at the</p> <p>25 printouts of the coated. Can you find the coated</p>	<p>156</p> <p>1 explain for a second -- I'm sorry, did you ask me</p> <p>2 a question, why it's every time 10.04 or 10.05 or</p> <p>3 10.06?</p> <p>4 Q. No.</p> <p>5 A. Because of its servo-control, so it</p> <p>6 always measures the real time. It says go for 10</p> <p>7 seconds, but it measures with the accuracy of</p> <p>8 hundredths of a second, so every time it's 10.06,</p> <p>9 10.05, 10.04. Every time it's slightly different.</p> <p>10 Q. I'm just going to move it over.</p> <p>11 A. Yeah, sure, sure.</p> <p>12 Q. What's going on here?</p> <p>13 A. I don't know what Erich did to it.</p> <p>14 Q. Now we're all the way on the left-hand</p> <p>15 side. See it says radius minus 13.136, 10.05.</p> <p>16 Looks like that's in the third column, right?</p> <p>17 A. Yeah, perfect. This is what we see now,</p> <p>18 right?</p> <p>19 Q. I don't know that we're seeing all the</p> <p>20 digits in the spreadsheet. Is there more digits</p> <p>21 in there?</p> <p>22 A. Maybe if we increase the width of the</p> <p>23 column. Yeah, now we see.</p> <p>24 Q. So, for example, if this is Sample 2,</p> <p>25 the test is actually starting at line 4694.</p>
<p>155</p> <p>1 in that file?</p> <p>2 Okay, there's the graph for the coated,</p> <p>3 right? Okay. Now, if you go to the data for the</p> <p>4 coated that we were looking at on the printouts,</p> <p>5 there's the data, right?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And we're looking at here part</p> <p>8 way down. If you go all the way to the top, right</p> <p>9 there, that is the top, this is the setting of the</p> <p>10 preload, right?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Now, could you go down and find</p> <p>13 where the preload stops and the test, if you will,</p> <p>14 if you want to call it that, the test part of it</p> <p>15 begins?</p> <p>16 A. Okay, one sec. I was there, and I just</p> <p>17 lost it. Erich, we need you, only your hands can</p> <p>18 work with this. I just saw it a second ago.</p> <p>19 Q. So that's where the actual --</p> <p>20 A. You'll see 10 seconds. 10 seconds were</p> <p>21 over, and preload was over. I'm looking at time.</p> <p>22 Q. Right. And -- okay. I see on the</p> <p>23 printout, see, for example, on column 2 it says</p> <p>24 No. 2, radius, velocity, duration?</p> <p>25 A. Because you know what, because I will</p>	<p>157</p> <p>1 A. Right.</p> <p>2 Q. Right, which would be this line here for</p> <p>3 Sample 2, see how it matches up 0.5, 13.629,</p> <p>4 30.3790. See that?</p> <p>5 A. Yeah.</p> <p>6 (DePuy Mitek Exhibit No. 396 was marked</p> <p>7 for identification.)</p> <p>8 BY MR. BONELLA:</p> <p>9 Q. Okay. I'm going to mark 396 as this</p> <p>10 page where it looks like the preload had finished</p> <p>11 and the testing is starting for at least</p> <p>12 Samples 1, 2 and 3. Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. So let's just look at Sample 2.</p> <p>15 Sample 2 at time zero, right --</p> <p>16 A. Yes.</p> <p>17 Q. -- the load is .5?</p> <p>18 A. Yes.</p> <p>19 Q. And time zero is measured in seconds,</p> <p>20 right?</p> <p>21 A. Yes.</p> <p>22 Q. And you said the load is going up .33</p> <p>23 uniformly per second?</p> <p>24 A. Yes.</p> <p>25 Q. So at time T equals 1, the load should</p>

<p style="text-align: right;">158</p> <p>1 be .83, right?</p> <p>2 A. .83, that's correct.</p> <p>3 Q. Okay. So let's scroll down and find</p> <p>4 1 second. That's in the I column, right, of the</p> <p>5 spreadsheet?</p> <p>6 A. Yes. Slowly, but surely.</p> <p>7 Q. Yes. Column I looks like around line</p> <p>8 5148 and 49 it reached about 1 second?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. And the load for line 5148 at</p> <p>11 1 second is .541.</p> <p>12 A. Yeah.</p> <p>13 Q. Shouldn't it be .83?</p> <p>14 A. It looks like there is an error in</p> <p>15 decimal.</p> <p>16 Q. In decimal?</p> <p>17 A. Yeah. It looks like it's increasing</p> <p>18 0.033 per second, not 0.33 per second. So if</p> <p>19 you --</p> <p>20 Q. Well, it's .541, so if that was the</p> <p>21 case, it would be .533?</p> <p>22 A. Yeah.</p> <p>23 Q. But it's not .533, right?</p> <p>24 A. No, it's not. Let's look at the area of</p> <p>25 2 seconds.</p>	<p style="text-align: right;">160</p> <p>1 Q. I'm going to label that as DePuy Mitek</p> <p>2 Exhibit 397, okay?</p> <p>3 A. Yes.</p> <p>4 (DePuy Mitek Exhibit No. 397 was marked</p> <p>5 for identification.)</p> <p>6 BY MR. BONELLA:</p> <p>7 Q. And you'll agree with me for Sample 2,</p> <p>8 after 1 second, the load was not .83?</p> <p>9 A. I agree.</p> <p>10 Q. Okay. So you'll agree with me that the</p> <p>11 sample -- the test was not being done in a uniform</p> <p>12 increasing load rate of .33 kilograms --</p> <p>13 A. Yes.</p> <p>14 Q. -- per second?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. Now, if we go to 10 seconds,</p> <p>17 let's go all the way down to the end.</p> <p>18 A. I brought it to 10 seconds, and at 10</p> <p>19 seconds it's 1.14.</p> <p>20 Q. It's what?</p> <p>21 A. 1.14.</p> <p>22 Q. The load is 1.14 at 10 seconds?</p> <p>23 A. Yes.</p> <p>24 Q. You're doing some math?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">159</p> <p>1 Q. Before you do that -- let's slow down a</p> <p>2 little bit. Before you do that, let's just find</p> <p>3 the page of the printout of that. Just hold that</p> <p>4 1 second spot for a minute.</p> <p>5 So we're looking at Sample 2, right?</p> <p>6 I'm going to mark -- I think is the page, if we</p> <p>7 can just verify that. For Sample 2, we were at</p> <p>8 1 second. If you look -- if you could just look</p> <p>9 at this -- before we get there, just slow down,</p> <p>10 okay?</p> <p>11 If we look at the page now, the</p> <p>12 printout, doesn't it correspond with the 1 second</p> <p>13 you were looking at on the graph?</p> <p>14 A. Yes.</p> <p>15 Q. See the time? This is Sample 2. Do you</p> <p>16 see that?</p> <p>17 A. Yes.</p> <p>18 Q. And time is .99, .79, goes to -- next</p> <p>19 one is 1.002.</p> <p>20 A. Yes.</p> <p>21 Q. And the loads are .541 and .546.</p> <p>22 A. Yes.</p> <p>23 Q. So this page is the data we were just</p> <p>24 looking at for the 1 second for Sample 2.</p> <p>25 A. Yes.</p>	<p style="text-align: right;">161</p> <p>1 Q. What did you come up with?</p> <p>2 A. It looks like the loading rate was</p> <p>3 different from what is stated in the report.</p> <p>4 Q. And what did you calculate?</p> <p>5 A. I calculated more like 0.06 kilogram per</p> <p>6 second.</p> <p>7 Q. Okay. Let's go to the 10 second page.</p> <p>8 Is this page the 10 second page that</p> <p>9 you're looking at for Sample 2?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. Let's mark that one 398.</p> <p>12 (DePuy Mitek Exhibit No. 398 was marked</p> <p>13 for identification.)</p> <p>14 BY MR. BONELLA:</p> <p>15 Q. Do you know if the load was actually</p> <p>16 uniformly increasing in this test?</p> <p>17 A. We can plot -- we can do plot load</p> <p>18 versus time in this Excel file and see how uniform</p> <p>19 it was.</p> <p>20 Q. Okay. When you set up this test, you</p> <p>21 were measuring -- you were applying a force that</p> <p>22 was programmed in, right?</p> <p>23 A. Yes.</p> <p>24 Q. And you were measuring strain; is that</p> <p>25 right?</p>

<p>162</p> <p>1 A. Yes.</p> <p>2 Q. Is there an assumption in the test that</p> <p>3 it's a uniform increase in --</p> <p>4 A. Yes.</p> <p>5 Q. And that assumption is wrong?</p> <p>6 A. No, I didn't say so.</p> <p>7 Q. I didn't say you did. I said if the</p> <p>8 assumption is wrong, how does that -- what does</p> <p>9 that do to the results?</p> <p>10 A. It would have no result -- no effect on</p> <p>11 the results.</p> <p>12 Q. Even if it wasn't uniform?</p> <p>13 A. Yes.</p> <p>14 Q. Why is that?</p> <p>15 A. Because we loaded sutures uniformly or</p> <p>16 not, whether we loaded with -- at the rate of .3</p> <p>17 kilogram per second or .03 kilogram per second, we</p> <p>18 saw clear differences between coated and uncoated,</p> <p>19 clear repeatable statistically different results</p> <p>20 for coated and uncoated sutures.</p> <p>21 Q. If you didn't load them uniformly,</p> <p>22 right, each one was loaded at a different rate --</p> <p>23 A. Yes.</p> <p>24 Q. -- you would generate different strains</p> <p>25 per time, right?</p>	<p>164</p> <p>1 Q. Yeah. You assumed that the diameter was</p> <p>2 constant along those lengths?</p> <p>3 A. No, we didn't make this assumption.</p> <p>4 Q. You didn't?</p> <p>5 A. No.</p> <p>6 Q. Well, you used -- did you use 0.65</p> <p>7 millimeters in calculating all the stiffness data</p> <p>8 that's presented in Table 2?</p> <p>9 A. Yes.</p> <p>10 Q. So did you actually measure along every</p> <p>11 point of the length of every suture?</p> <p>12 A. No.</p> <p>13 Q. Okay. So you did some measurements?</p> <p>14 A. We assumed that this data is the average</p> <p>15 diameter, but we did not assume -- we did not make</p> <p>16 any assumptions on each cylinder being ideally --</p> <p>17 ideally cylindrical because nothing is ideal in</p> <p>18 this life.</p> <p>19 If you want to characterize cross</p> <p>20 section of the cylinder, you have to deal with</p> <p>21 average parameters for the cylinder.</p> <p>22 Q. Well, doesn't the test assume that</p> <p>23 applying a -- you measured diameters along the</p> <p>24 length of some specimens for the pliability tests?</p> <p>25 A. Yes.</p>
<p>163</p> <p>1 A. Yes.</p> <p>2 Q. So the graphs that generated would not</p> <p>3 be correct?</p> <p>4 A. No, the graphs would still stay because</p> <p>5 this graph is just one column versus another</p> <p>6 column. You have column -- we just looked with</p> <p>7 you at the computer. You have column force, and</p> <p>8 you have column strain, and you just plot force</p> <p>9 versus strain or strain versus force, and whether</p> <p>10 it was increasing uniformly or not, it cannot</p> <p>11 change this graph.</p> <p>12 Q. Let me ask you a different question. If</p> <p>13 the loads didn't increase at a uniform rate, at</p> <p>14 the same uniform rate on each sample, you can't</p> <p>15 really compare the graphs to each other?</p> <p>16 A. If for every sample the rates were</p> <p>17 different, it would jeopardize the results.</p> <p>18 Q. Okay. You assumed in this test that the</p> <p>19 diameter was constant along the length of each</p> <p>20 specimen, right?</p> <p>21 A. I didn't understand your question.</p> <p>22 Q. Each specimen, for the pliability test,</p> <p>23 you assumed that the diameter --</p> <p>24 A. We recall specimens at 50 millimeter</p> <p>25 from the suture.</p>	<p>165</p> <p>1 Q. And you calculated an average diameter?</p> <p>2 A. This is what we planned to do, but we</p> <p>3 didn't have to do it because many measurements</p> <p>4 that we did produced the same result, .65.</p> <p>5 Q. Who measured the diameter?</p> <p>6 A. Michael Vinogradov.</p> <p>7 Q. How much experience does he have in</p> <p>8 measuring suture diameters?</p> <p>9 A. In measuring suture diameters, his</p> <p>10 experience is very, very limited, but in measuring</p> <p>11 diameters of cylinders, he has plenty of</p> <p>12 experience.</p> <p>13 Q. How about in measuring diameter of</p> <p>14 specimens on the order of the size of a suture?</p> <p>15 A. We have lots of experience for this.</p> <p>16 Q. No, him personally.</p> <p>17 A. Him personally.</p> <p>18 Q. Does the device that you used to measure</p> <p>19 diameter, specifically what was the device used?</p> <p>20 A. Caliper.</p> <p>21 Q. What's the type and name of the caliper?</p> <p>22 A. Made by a Japanese company called</p> <p>23 Mitutoyo, but I don't remember the particular</p> <p>24 model.</p> <p>25 Q. Was it digital or --</p>



<p style="text-align: right;">166</p> <p>1 A. Yeah, digital, sure.</p> <p>2 Q. Okay. How many decimal places does it</p> <p>3 read out in?</p> <p>4 A. I do not remember.</p> <p>5 Q. Okay. Do you know what its accuracy or</p> <p>6 sensitivity is?</p> <p>7 A. I do not remember.</p> <p>8 Q. Do you know if it's designed to measure</p> <p>9 specimens on the order of sutures? I'm sorry, do</p> <p>10 you know if the caliper that was used is</p> <p>11 specifically designed to measure suture diameters?</p> <p>12 A. I know that it was not designed</p> <p>13 specifically for sutures. It's just a general</p> <p>14 engineering caliper that we use in our lab. We</p> <p>15 have several of them. We ordered them together,</p> <p>16 they are from the same bunch, Mitutoyo calipers,</p> <p>17 but I don't believe that Mitutoyo targets suture</p> <p>18 market with those calipers.</p> <p>19 Q. Okay. Doesn't the test -- the tests</p> <p>20 that you're doing -- well, are you saying that</p> <p>21 you -- did you verify that the specimens that were</p> <p>22 tested in the pliability tests were actually</p> <p>23 circular in diameter?</p> <p>24 MR. TAMBURRO: Objection, vague.</p> <p>25 THE WITNESS: No, we did not.</p>	<p style="text-align: right;">168</p> <p>1 on coated and uncoated, because in the beginning</p> <p>2 we were not sure whether coating would introduce</p> <p>3 some thickness, so we did it very carefully.</p> <p>4 MR. TAMBURRO: Do you want to break for</p> <p>5 lunch soon?</p> <p>6 MR. BONELLA: Yeah. Let's just finish</p> <p>7 this up.</p> <p>8 THE WITNESS: It's about end. Let's</p> <p>9 finish.</p> <p>10 (DePuy Mitek Exhibit Nos. 399 and 400</p> <p>11 were marked for identification.)</p> <p>12 BY MR. BONELLA:</p> <p>13 Q. I'm going to show you DePuy Mitek</p> <p>14 Exhibit 399 and DePuy Mitek Exhibit 400. I ask</p> <p>15 you if you've ever seen these documents before?</p> <p>16 A. I don't remember ever seeing these</p> <p>17 documents.</p> <p>18 Q. Okay. Do you see where -- they're from</p> <p>19 Pearsalls?</p> <p>20 A. Yes.</p> <p>21 Q. And they're dated February 17th, 2006.</p> <p>22 Do you see that?</p> <p>23 A. Where shall we see the date?</p> <p>24 Q. Down the bottom on the left-hand side.</p> <p>25 A. Oh, yes.</p>
<p style="text-align: right;">167</p> <p>1 BY MR. BONELLA:</p> <p>2 Q. Okay. So there was an assumption that</p> <p>3 they were circular in diameter?</p> <p>4 A. They looked circular.</p> <p>5 Q. Okay, but they're very small?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And it was also assumed that</p> <p>8 they're circular in diameter along the entire</p> <p>9 length of the specimen, the 50 millimeters that</p> <p>10 was tested in pliability tests?</p> <p>11 A. We did not need this assumption. If you</p> <p>12 are talking about our calculations of the moment</p> <p>13 of inertia where we used diameter of the cylinder,</p> <p>14 yes, it was assumed that average diameter was .65,</p> <p>15 but we did not need to go and to measure each and</p> <p>16 every cross section over the length of</p> <p>17 50 millimeters, because in practical engineering,</p> <p>18 you just need to have the average diameter for</p> <p>19 your calculations of the moment of inertia.</p> <p>20 Q. Okay. How many measurements did you</p> <p>21 take of diameter?</p> <p>22 A. I believe I already answered. We did</p> <p>23 minimum 10, 12 on the coated, and minimum 10, 12</p> <p>24 on the uncoated.</p> <p>25 One of the -- why we did it separately</p>	<p style="text-align: right;">169</p> <p>1 Q. And do you see on Exhibit 399, do you</p> <p>2 see it says -- underneath here it says coated with</p> <p>3 Nusil Med2174 Silicone?</p> <p>4 A. Yes.</p> <p>5 Q. And if you look at Exhibit 400, in the</p> <p>6 product line, third line of the document, it says</p> <p>7 Blue Fibre Wire Uncoated. Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. You don't know if these documents</p> <p>10 pertain to the samples that you tested, do you?</p> <p>11 A. I don't know.</p> <p>12 Q. They weren't provided to you?</p> <p>13 A. They have not been provided.</p> <p>14 Q. If you look at Exhibit 399 and look</p> <p>15 under the diameter column or row, there's an</p> <p>16 average/mid/max?</p> <p>17 A. Yes.</p> <p>18 Q. And the average diameter was .586,</p> <p>19 minimum was .570, and the max was .599.</p> <p>20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. This is for a coated sample. It's</p> <p>23 different than what you assumed -- or you used,</p> <p>24 I'm sorry, .65?</p> <p>25 A. Yes.</p>

<p style="text-align: right;">170</p> <p>1 Q. Okay. Can you explain why there would 2 be a difference if this applies to the same 3 suture?</p> <p>4 MR. TAMBURIO: Objection, calls for 5 speculation.</p> <p>6 THE WITNESS: I cannot explain. I don't 7 know --</p> <p>8 BY MR. BONELLA:</p> <p>9 Q. And you agree that the .65 that you used 10 is above the maximum that was measured at least 11 for this sample in Exhibit 399?</p> <p>12 A. Yes.</p> <p>13 Q. If you look at Exhibit 400, for the 14 uncoated the diameter average was .600 15 millimeters, the min was .570, and the max was 16 .635. Do you see that?</p> <p>17 A. Yes, I do.</p> <p>18 Q. And so for this uncoated sample in 19 Exhibit 400, the maximum diameter that was 20 measured is less than the diameter that you used, 21 right?</p> <p>22 A. Yes.</p> <p>23 Q. Can you explain that?</p> <p>24 A. No, I cannot.</p> <p>25 Q. And do you see how the uncoated in</p>	<p style="text-align: right;">172</p> <p>1 the deposition of Dr. Mukherjee or from some 2 rebuttal or report of Dr. -- of your expert 3 witness.</p> <p>4 Q. I'll show you the next exhibit.</p> <p>5 THE VIDEOGRAPHER: I need to change. It 6 takes 20 seconds.</p> <p>7 MR. BONELLA: That's all right, keep 8 going.</p> <p>9 (DePuy Mitek Exhibit No. 401 was marked 10 for identification.)</p> <p>11 BY MR. BONELLA:</p> <p>12 Q. DePuy Mitek Exhibit 401 -- I'm sorry, I 13 labeled the inside page, but it's a 4-page 14 document. Part of it is not from the same 15 document, but the last page is suture size and 16 diameter chart. Do you see that?</p> <p>17 A. Yes, I do.</p> <p>18 MR. TAMBURIO: I'm sorry, are you 19 representing this as a USP chart?</p> <p>20 MR. BONELLA: The last page is.</p> <p>21 MR. TAMBURIO: The last page is.</p> <p>22 BY MR. BONELLA:</p> <p>23 Q. Okay, if you go to -- one column says 24 non-absorbable and synthetic absorbable sutures, 25 and there's a number 2. Do you see that?</p>
<p style="text-align: right;">171</p> <p>1 Exhibit 400 and the coated in 399 had different 2 measurements for average/minimum/maximum 3 diameters?</p> <p>4 A. Yes -- no. I see the same minimums, but 5 different averages and maximums.</p> <p>6 Q. Yes, I'm sorry, thank you. But didn't 7 find any difference in the diameters when you 8 measured them?</p> <p>9 MR. TAMBURIO: Objection, 10 mischaracterizes testimony.</p> <p>11 BY MR. BONELLA:</p> <p>12 Q. I'm sorry, did you find differences in 13 diameters between the coated and uncoated samples 14 that you tested in the pliability tests?</p> <p>15 A. We specifically looked for it, and we 16 didn't find the differences.</p> <p>17 Q. Okay. Now, are you familiar with the 18 USP sizing for diameters?</p> <p>19 A. No, I am not.</p> <p>20 Q. Okay. Are you familiar with a No. 2 21 designation for suture?</p> <p>22 A. No.</p> <p>23 Q. Did you ever hear of a diameter range 24 for a No. 2 suture?</p> <p>25 A. No. Maybe I heard about it either from</p>	<p style="text-align: right;">173</p> <p>1 A. Yes.</p> <p>2 Q. And it has diameter limits of .5000 to 3 .599 for that. Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. And the diameter you used of .655 is 6 above those diameter limits, right?</p> <p>7 A. Yes.</p> <p>8 Q. Did you test any sutures other than 9 No. 2 size suture?</p> <p>10 A. I did not test any sutures rather than 11 those spools I received from the law firm.</p> <p>12 Q. If the diameter of the coated and 13 uncoated were different, that would change the 14 pliability test data stiffness that's presented in 15 table -- on page 4 of your report, correct?</p> <p>16 A. That's correct.</p> <p>17 Q. Okay, you want to break for lunch?</p> <p>18 MR. TAMBURIO: Sure.</p> <p>19 THE VIDEOGRAPHER: This is the end of 20 Tape 2, beginning of Tape 3. Off the record at 21 12:45:46.</p> <p>22 (Lunch break taken.)</p> <p>23 THE VIDEOGRAPHER: This is the beginning 24 of Tape 3 in the deposition of Dr. Norm V. Gitis. 25 On the record -- excuse me, can we go off the</p>

44 (Pages 170 to 173)

<p>174</p> <p>1 record? Off the record at 1:43:13.  2 (Pause in the proceedings.)  3 THE VIDEOGRAPHER: This is Tape 3 in the  4 deposition of Dr. Norm V. Gitis. On the record at  5 1:44:58.  6 BY MR. BONELLA:  7 Q. Were there any recordation of the  8 diameter measurements that you said were made? Is  9 there anywhere that was recorded?  10 A. No, it was not.  11 Q. According to the data, it shows for the  12 pliability tests that you had eight samples of  13 coated and uncoated that were reported in tests?  14 A. Yes.  15 Q. Okay. Other than the eight, did you do  16 any other samples that aren't recorded there?  17 A. No.  18 Q. Why did you choose eight?  19 A. Because among the references we cited,  20 some people tested five, some seven, some ten, so  21 we saw eight as somewhere in the middle.  22 Q. Okay. Any other reason?  23 A. Huh?  24 Q. Any other reason?  25 A. That's about it.</p>	<p>176</p> <p>1 A. No.  2 Q. You just orally told him?  3 A. Yes.  4 Q. Okay. And do you know how you arrived  5 at the .33 kilogram per second?  6 A. It was from some -- again, from the same  7 references. From one of the references cited.  8 Q. Either the --  9 A. Rodeheaver or --  10 Q. Bizwada patent?  11 A. Yeah.  12 Q. So this pliability test is actually --  13 the test you did is actually a tension test, isn't  14 it?  15 A. It's a pliability test.  16 Q. It's also a tension test, right?  17 A. Yes.  18 Q. And in order for it to be a pliability  19 test, certain assumptions have to be true, right?  20 A. Yes.  21 Q. Is one of the assumptions that the  22 compressive and tensile modulus of the specimen --  23 let me rephrase that.  24 Is one of the assumptions that the  25 compressive and tensile moduli are the same for</p>
<p>175</p> <p>1 Q. Who actually wrote this report?  2 A. I did.  3 Q. You did? So you put the 0.33 kilogram  4 per second uniform increase in?  5 A. Yes.  6 Q. Where did you get that from?  7 A. From my engineers. They gave me the  8 number.  9 Q. You got that from them?  10 A. Yeah.  11 Q. Did you program yourself, did you put  12 into the machine the rate at which the load should  13 go up?  14 A. No, I did not.  15 Q. Do you have any documents where you  16 specified the parameters for the test that should  17 be inputted into the machine?  18 A. Yes. If it's not provided in the Excel  19 files -- what documents do you mean?  20 Q. Like, for example, if you wrote, either  21 typed up or handwritten, said to your assistant,  22 said, okay, the pliability tests, here is how I  23 want you to run it, 50 centimeter gauge length,  24 uniform increase of load at this rate, preload of  25 this. Did you make some kind of document?</p>	<p>177</p> <p>1 the specimen?  2 A. It was not specifically the assumption  3 for this test.  4 Q. You didn't assume that one way or the  5 other?  6 A. No, we did not.  7 Q. You didn't consider it?  8 A. Again, as we discussed before lunch, we  9 just decided to use the same test as our  10 customers.  11 Q. So you didn't use -- you didn't consider  12 whether that was an assumption that goes into  13 applying this test for stiffness then?  14 MR. TAMBURRO: Objection, vague.  15 THE WITNESS: No, we did not spend much  16 time on considering assumptions of our customers.  17 BY MR. BONELLA:  18 Q. If the compressive and tensile moduli  19 for the FiberWire specimens you tested are not the  20 same, how would it affect the pliability test  21 results that you've prepared?  22 A. It's hard to say. Depends on their  23 levels.  24 Q. If they're different, if the compressive  25 and tensile moduli for the FiberWire samples are</p>